K082400

2/3/09

Subject: 510 (K) SUMMARY

510 (K) Number: K082400

Contact Name: Mike Jablonski, General Manager
Joe Baumtrog, Project Coordinator

Proprietary Name: Culligan Soft Water Service Company, Deionizer, and Carbon Exchange Service for Hemodialysis

Common Name: DI and Carbon Exchange Tanks for Hemodialysis

Classification Name: Carbon and Deionized Dialysis Exchange Tanks for Hemodialysis

Classification: Class II Medical Device under 21 CFR 876.5665
Panel: Gastroenterology
Product Code: FIP

Intended Use: The Culligan Soft Water Service Company Deionizer and Carbon Exchange tanks are primary or temporary devices to provide water for hemodialysis applications per the requirements of ANSI/AAMI RD62. These tanks remove chlorine, chloramines, total organic carbons and total dissolved solids from water used to dilute dialysis concentrate to form dialysate, in reprocessing of hemodialyzers, as supply water to the dialysis machines and equipment rinse and disinfection. Upon exhaustion, these tanks will be replaced with other tanks containing newly regenerated resin, or with new resin altogether. These tanks are components of a larger water treatment system employing adequate pre-treatment and post-treatment sections. Culligan's tanks are not to be used alone.

Device Description: The Culligan Soft Water Service Company, Deionizer and Carbon Exchange Service for Hemodialysis includes carbon filtration for the removal of chlorine and chloramines and deionizer (DI) exchange tanks for the removal of contaminants from the water through an ion exchange process to provide AAMI quality water for hemodialysis applications.

Statement of Substantial Equivalence: The Culligan Soft Water Service Company, Deionizer and Carbon Exchange Service for Hemodialysis is substantially equivalent in intended use, function, and technology to the Ameriwater Dialysis Deionizer Exchange Service (K991519).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2009

Mr. Mike Jablonski
General Manager
Culligan Soft Water Service Company
6030 Culligan Way
MINNETONKA MN 55345-5970

Re: K082400
Trade/Device Name: Carbon and Deionized Dialysis Exchange Tanks for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: January 28, 2009
Received: January 30, 2009

Dear Mr. Jablonski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K082400

Device Name: Carbon and Deionized Dialysis Exchange Tanks for Hemodialysis

Culligan Tank Model Numbers:

Carbon Tanks	Mixed-Bed Tanks	Duo-Bed Tanks
DRM50	UDM50	DC9
DRM9	UDM9	DA9
DRM4	UDM4	DC4
		DA4

Indications For Use: The Culligan Soft Water Service Company Deionizer and Carbon Exchange tanks are primary or temporary devices to provide water for hemodialysis applications per the requirements of ANSI/AAMI RD62. These tanks remove chlorine, chloramines, total organic carbons and total dissolved solids from water used to dilute dialysis concentrate to form dialysate, in reprocessing of hemodialyzers, as supply water to the dialysis machines and equipment rinse and disinfection. Upon exhaustion, these tanks will be replaced with other tanks containing newly regenerated resin, or with new resin altogether. These tanks are components of a larger water treatment system employing adequate pre-treatment and post-treatment sections. Culligan's tanks are not to be used alone.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082400